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NOTICE OF ALLOWANCE AND FEE(S) DUE

MERCK AND CO., INC

07/22/2009

NC

P O BOX 2000 RAHWAY, NJ 07065-0907 EXAMINER

RODRIGUEZ-GARCIA, VALERIE

ART UNIT PAPER NUMBER

ART UNIT

DATE MAILED: 07/22/2009

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------|-------------|----------------------|---------------------|------------------|--|
| 10/586.381 | 07/18/2006 | Claude Dufresne | MCI02P | 2797 | |

TITLE OF INVENTION: NITRIC OXIDE RELEASING PRODRUGS OF DIARYL-2-(5H)-FURANONES AS CYCLOOXYGENASE-2 INHIBITORS

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 10/22/2009 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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| appropriate. All further indicated unless corrects maintenance fee notifica | correspondence includir ed below or directed oth | or transmitting the 18 ig the Patent, advance herwise in Block 1, by | orders and notification of r (a) specifying a new corre | naintenance fees wi pondence address; | ll be and/or | mailed to the current (b) indicating a sepa | corresp arate "F | pondence address as 'EE ADDRESS" for |
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| | | | | | | | | (Depositor's name) |
| | | | <u> </u> | | | | | (Signature) |
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| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | | ATTO | RNEY DOCKET NO. | CON | FIRMATION NO. |
| 10/586,381 TITLE OF INVENTION | 07/18/2006 : NITRIC OXIDE RELE | EASING PRODRUGS | Claude Dufresne OF DIARYL-2-(5H)-FURAI | NONES AS CYCL | .00X | MC102P YGENASE-2 INHIB | ITORS | 2797 |
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| EXAM | IINER | ART UNIT | CLASS-SUBCLASS |] | | | | |
| RODRIGUEZ-GA | RCIA, VALERIE | 1626 | 514-509000 | | | | | |
| "Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A | ondence address (or Cha B/122) attached. ication (or "Fee Address 22 or more recent) attach ND RESIDENCE DAT/ less an assignce is ident h in 37 CFR 3.11. Comp | nge of Correspondence Indication form and Use of a Custome A TO BE PRINTED O | or agents OR, alternati | 3 registered patent vely, e firm (having as a agent) and the name rneys or agents. If n printed. | memb s of up o nam | er a 2 2 5 to 6 to 6 to 7 to 7 to 7 to 7 to 7 to 7 | | n has been filed for |
| Please check the appropr | iate assignee category or | categories (will not be | printed on the patent): | Individual 🚨 Cor | porati | on or other private gr | oup enti | ity Government |
| 4a. The following fee(s) Issue Fee Publication Fee (N | vo small entity discount p | permitted) | 4b. Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo | d. Form PTO-2038 | is atta | ched. | | |
| - 11 | s SMALL ENTITY state | is. See 37 CFR 1.27. | ☐ b. Applicant is no lon | | | | | |
| NOTE: The Issue Fee an interest as shown by the | d Publication Fee (if req records of the United Sta | uired) will not be accep tes Patent and Tradem | oted from anyone other than t ark Office. | he applicant; a regis | tered a | ittorney or agent; or the | e assig | nee or other party in |
| Authorized Signature | | | | Date | | | | |
| Typed or printed name | | | | Registration No | э | | | |
| This collection of inform an application. Confiden submitting the complete this form and/or suggests Box 1450, Alexandria, V Alexandria, Virginia 223 | nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC k13-1450. | EFR 1.311. The information U.S.C. 122 and 37 CF USPTO. Time will widen, should be sent to D NOT SEND FEES O | ation is required to obtain or a R 1.14. This collection is est ary depending upon the indiv the Chief Information Office R COMPLETED FORMS To | etain a benefit by th imated to take 12 m idual case. Any cor er, U.S. Patent and T D THIS ADDRESS. | e publ inutes nment Traden SENI | ic which is to file (an- to complete, includir s on the amount of ti- nark Office, U.S. Dep O TO: Commissioner | I by the ig gathe me you artment for Pate | USPTO to process) ering, preparing, and require to complete of Commerce, P.O. ents, P.O. Box 1450, |

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| 210 | 7590 | 07/22/2009 | | EXAMINER | | | |
| MERCK AN | ID CO., IN | IC . | | RODRIGUEZ-GARCIA, VALERIE | | | |
| P O BOX 200 | | | | ART UNIT | PAPER NUMBER | | |
| RAHWAY, NJ 07065-0907 | | | | | | | |
| | | | | DATE MAILED: 07/22/2009 | | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 537 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 537 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/586,381 DUFRESNE ET AL. Notice of Allowability Examiner Art Unit VALERIE RODRIGUEZ-GARCIA 1626 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. 1. X This communication is responsive to response to Electio/Restriction requirement received on April 14, 2009. The allowed claim(s) is/are 1-7,11,12 and 14-19. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. ___ 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. X Examiner's Amendment/Comment Paper No./Mail Date 07/18/2006 8. X Examiner's Statement of Reasons for Allowance 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material 9. ☐ Other ... Valerie Rodriguez-Garcia Art Unit 1626

Application/Control Number: 10/586,381

Art Unit: 1626

DETAILED ACTION

I. Action Summary

Receipt of the response to Election/Restriction requirement and remarks filed on April 14, 2009 is acknowledged. After the following Examiner's amendment, claims 1-7, 11, 12 and 14-19 are in condition for allowance. The Restriction/Election Requirement of 03/17/2009 is hereby WITHDRAWN.

II. Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a phone conversation with Mr. Curtis Panzer on June 29, 2009.

The application has been amended as follows:

In claim 6, line 1, after "disease" please ADD, --wherein the disease is selected from the group consisting of osteoarthritis, rheumatoid arthritis and chronic pain--.

In claim 6, please **DELETE** [susceptible to treatment with a non-steroidal antiinflammatory agent].

In claim 7, lines 2 and 3, please DELETE [cardiovascular].

Please, DELETE claims 8, 9, 10 and 13.

In claims 11, 12, 14 and 17, please **DELETE** [claim 10] and **REPLACE** with -- claim 7--.

Application/Control Number: 10/586,381

Art Unit: 1626

III. Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The closest prior art is Berthelette *et al.* (US 7,199,154 B2, equivalent of WO 2004/011421). The prior art describes similar compounds with one nitrate group. The instantly claimed compounds have two nitrate groups. However, it is not obvious to add another nitrate group to the products of the prior art and exactly in the claimed position. Therefore, the prior art does not anticipate, or render obvious, the products as described in the instantly claimed invention. Therefore, claims 1-7, 11, 12 and 14-19 are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

IV. <u>Telephone Inquiry</u>

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE RODRIGUEZ-GARCIA whose telephone number is (571)270-5865. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/ Primary Examiner, Art Unit 1626

VRG Art Unit 1626